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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,659	01/28/2002	Brian William James		2344
75	90 08/21/2003			
Ranjana Kadle Hodgson Russ			EXAMINER	
Suite 2000			LILLING, HERBERT J	
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Buffalo, NY 14203-2391			ART UNIT	PAPER NUMBER
			1651	7
			DATE MAILED: 08/21/2003	`/

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		09/914,659	JAMES ET AL.				
		Examiner	Art Unit				
		HERBERT J LILLING	1651				
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)	Responsive to communication(s) filed on <u>01/2</u>	<u>8/2002</u> .					
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims							
4)	Claim(s) 1,3-22 and 25-29 is/are pending in the	e application.					
4	4a) Of the above claim(s) is/are withdrawn from consideration.						
	Claim(s) is/are allowed.						
	6) ☐ Claim(s) is/are rejected.						
	7) Claim(s) is/are objected to.						
8) Claim(s) 1, 3-22 and 25-29 are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)[∑	☑All b) Some * c) None of:						
	1. Certified copies of the priority documents	have been received.					
2	2. Certified copies of the priority documents	have been received in Applicatio	n No				
Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
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14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) ☐ The translation of the foreign language provisional application has been received.							
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(		, , ,					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)							
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## **DETAILED ACTION**

- 1. Receipt is acknowledged of the preliminary amendment filed January 28, 2002 in this application filed under a 371 of PCT/GB00/00760 International Filing Date: 03/02/2000.
- 2. Claims 1, and 3-22 and 25-28 plus new claim 29 are now pending in this instant application.

Claims 2 and 23-24 have been cancelled.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-13 and 22, drawn to a method of culturing mycobacteria in the presence of a detergent.

Group II, claim(s) 14- 21, drawn to a growth medium for the culturing mycobacteria.

Group III, claims 25-29, drawn to a method of culture of a mycobacteriophage.

4. The groups listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons Invention I does not contain the same special technical features of Group II. Group I does not require the specifics of Group III.

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5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A. Whereby the mycobacteria is selected from:
  - a. M. tuberculosis;
  - b. M. bovis;
  - c. M. vacae.
- B. Whereby the growth medium comprises a carbon source is selected from
  - i. glucose;
  - ii. glycerol;
  - iii. amino acid;
- C. Whereby the growth medium comprises a nitrogen source is selected from mm. amino acid [further an election of one species from claim 19] nn. ammonium salt.
- D. Whereby the growth medium is comprises the following:
  - aa. carbon source;
     and whereby the growth medium comprises a carbon source
     is selected from
    - i. glucose;

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ii. glycerol;

iii. amino acid; plus

a mitogen

plus

trace element

plus

nitrogen source whereby the growth medium comprises a nitrogen source is selected from

mm. amino acid [further an election of one species from claim 19]

nn. ammonium salt

plus

detergent in the amount greater than 0.1% (v/v).

bb. above aa plus further a vitamin/cofactor selected from

ddd. Inositol;

eee. Thiamine;

fff. Calcium pantothenate;

ggg. Co-enzyme A;

hhh. Nicotinamide;

iii. biotin;

jjj. DL-thiocitic acid;

kkk. Mixture of above ddd-jjj - [please specify the mixture]

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cc. above aa plus further one or more components selected from:

uu. one ingredient from

uua. sodium hydroxide

uub. Glutathione

uuc. Glycerol;

uud. Haemin;

uue. Sodium pyruvate;

uuf. Alpha-ketoglutarate.

vv. more than one ingredient from above uu [please specify the ingredients].

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention I, II or III and an election of one species from each of the above A, B, C and D (if appropriate to the elected invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is requested to contact this Examiner if assistance is needed for election.

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- 6. Applicant has inserted in Claim 1 the following expression "other than *M. avium*" which this Examiner cannot find in the specification. Applicant is requested to support this expression prior to any examination drawn to Invention I.
- 7. It is noted that Claim 1 contains the phrase "A method of culture of mycobacteria" which appears to be in error.
- 8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is** (703) 308-2034 and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL (703) 308-2034 Art Unit <u>1651</u> August 20, 2003

Dr. Herbert J. Lilling Primary Examiner

Group 1600 Art Unit 1651